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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/782,534 | 02/13/2001 | Andrew H. Cragg | 9500100.APP | 1509 |

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| EXAMINER |
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ALI, SHUMAYA B

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| ART UNIT | PAPER NUMBER |
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3743

DATE MAILED: 11/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/782,534

Applicant(s)

CRAGG ET AL.

Examiner

Shumaya B. Ali

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 48 and 49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 48 and 49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: detailed action.

DETAILED ACTION

Response to Arguments

1. In response to applicant's arguments, the recitation "for cutting material inside an intervertebral spine disc" on page 11 has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).
2. **Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.**
3. Applicant's arguments with respect to claims 1-5, and 48-49 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. **Claims 1-5 and .48-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiley et al. US Patent No. 6,440,138 B1 in view of McFarlane Us Patent No. 4,046,144.**

5. **Regarding claim 1**, Reiley et al. discloses an apparatus fully capable of cutting material inside an intervertebral spinal disc, the intervertebral spinal disc having a disc body formed of a nucleus and, annulus, the apparatus comprising:

a. An elongated discectomy instrument (such as 22, 110, etc. and their respective associated components) having a discectomy instrument body extending between a discectomy instrument proximal end and instrument distal end, a cutting head (such as 22, 110, etc.) Located in a distal

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portion of the discectomy instrument, the instrument body and cutting head dimensioned to fit within and to extend through the axial bore; and

b. An anterior tract sheath having a shaped distal end fully capable of engaging an anterior surface of the sacral vertebral body;

c. Wherein the shaped distal end of the anterior tract sheath is fully capable of facilitating the anchoring of the anterior tract sheath onto the anterior surface of the sacral vertebral body from a para coccygeal skin access point.

Regarding the phrase, "through a trans-sacral axial bore extending cephalad and axially from a sacral position of a sacral vertebral body through one or more vertebral body and through, a vertebral body endplate and axial disc opening into the nucleus of the intervertebral spinal disc", this functional language does not hold patentable weight in an apparatus claim. Thus, given the structure of Reiley et al. the device is fully capable of performing the function as claimed in a bore made in any orientation.

Reiley et al. discloses the apparatus comprising all the limitations recited in claim 1, with the exception of a beveled distal end of the anterior tract sheath. However, the use of beveled-edge sheath was known at the time the invention was made. Specifically, McFarlane teaches the use of beveled end 53 at the distal end of the tubular body 22 for easing the tubular body in entering on venipuncture (col.3 lines 68-69 and col.4 lines 1) or the body of the patient. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the distal end of the anterior tract sheath of Reiley et al. by altering it to have a beveled shape because it is well known in the art, as taught by McFarlane, to aid the insertion of discectomy instrument into the body of a patient.

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6. **Regarding claim 2**, Reiley et al. discloses that as applied to claim 1, as well as, aspiration means for aspirating the disc cavity or disc space, as recited in column 7, lines 10-25, for example.

7. **Regarding claim 3**, Reiley et al. discloses that as applied to claim 1, as well as, a cutting head having a fragmenting element for fragmenting the nucleus or annulus into fragments, as recited in columns, 1-7.

8. **Regarding claim 4**, Reiley et al. discloses that as applied to claim 3, as well as aspiration means for aspirating nucleus or annulus fragments from the disc cavity or disc space, as recited in column 7, lines 10-25, for example.

9. **Regarding claim 5**, Reiley et al. discloses that as applied to claim 3, as well as, irrigation means for delivering irrigation fluid into the disc cavity or disc space', and aspiration means for aspirating the nucleus fragments and irrigation fluid from the disc cavity or disc space, as recited in column 7, lines 10-25, for example.

10. **Regarding claim 48**, Reiley et al. discloses that as applied to claim 1, as well as, means for accessing (via 34 and 12) a sacral position of a sacral vertebral body', and means operable from the accessed sacral position for boring a trans-sacral axial bore cephalad and axially through a series of adjacent vertebral bodies and any intervening spinal discs, as recited in columns 2-7. Father, Applicant is reminded that functional language does not hold patentable weight in an apparatus claim. Further, the apparatus of Reiley et al. is fully capable of performing the function as claimed.

11. **Regarding claim 49**, Reiley et al. discloses that as applied to claim 1, as well as, means for accessing an anterior surface of the sacral vertebral body (via 34 and 12). and means operable

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from the accessed anterior surface for boring a trans-sacral axial bore cephalad and axially through the vertebral bodies of a series of adjacent vertebral bodies and any intervening spinal discs and into or through the selected spinal disc providing at least a caudal axial disc opening into the nucleus of the selected spinal disc, as recited in columns 2-7. Further, Applicant is reminded that functional language does not hold patentable weight in an apparatus claim. Further, the apparatus of Reiley et al. is fully capable of performing the function as claimed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-F 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shumaya B Ali

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Examiner
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10/31/05

Henry Bennett
Supervisory Patent Examiner
Art Unit 3700